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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO.       |
|--|-------------|----------------------|------------------------------|------------------------|
| 10/804,895   | 03/19/2004  | Madhavan Pisharodi   | PISA,015                     | 8181                   |
| 7590<br>Mark Wisner<br>c/o Wisner & Associates<br>Suite 400<br>1177 West Loop South<br>Houston, TX 77027 |             |                      | EXAMINER<br>PREBILIC, PAUL B |                        |
|  |             |                      | ART UNIT<br>3774             | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>03/19/2009      | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/804,895

**Applicant(s)**

PISHARODI, MADHAVAN

**Examiner**

Paul B. Prebille

**Art Unit**

3774

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 11 and 19-35 is/are pending in the application.  
4a) Of the above claim(s) 1, 3 and 11 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 2 and 19-35 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2008 has been entered.

***Election/Restrictions***

Claims 1, 3, and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

***Claim Objections***

Claims 2, 19, 28, and 31-35 are objected to because of the following informalities:

Regarding claim 2, on line 11, "the longitudinal axis" is unclear because the implant has a height and is elongate, yet the disclosed rotation is not along the height axis but along the insertion axis. The Applicant could insert change "the longitudinal axis" to "the insertion axis" in order to overcome this objection.

With regard to claims 19, 28, and 32-35, the step of "resisting" is confusing since this is not a manipulative step but rather, a feature provided by the implant structure.

With regard to claim 31, the steps of "maintaining" and "biasing" are confusing because there are not manipulative steps, but rather, features provided by the implant structure.

Regarding claims 31, 33, 34, and 35, the steps of "maintaining", "resisting", and "limiting" are all due to physical features of the device and are not manipulative steps. Furthermore, these steps may lack original support.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 24, 25, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisharodi (US 5,123,926). Pisharodi anticipates the claim language where the step of removing a portion of a disk as claimed is disclosed on column 2, lines 11-18 of Pisharodi, the elongate implant as claimed is the disk prosthesis (2) of Pisharodi, the insert as claimed is band (14) of Pisharodi, the inserting step as claimed is disclosed on column 3, lines 32-57, the restraining step as claimed is done by the band (14) of Pisharodi and the resisting rotation step is done by the shape of the implant as being larger on the top and bottom as compared to the sides; see Figure 2.

Regarding claim 35, the Applicant is directed to see column 3, lines 55-57.

Claims 19 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Perren et al (US 6,019,793). Perren anticipates the claim language where the inserting

step as claimed is met by the inserting step of Perren (see column 3, line 66 to column 4, line 2 and see column 1, line 55 to column 2, line 12), the insert as claimed is one of either the upper plate (1) or lower plate (1), and the biasing step as claimed is done by means (4) of Perren. The upper plate (1) or lower plate (2) is movably mounted relative to the rest of the implant in that the means (4) allows relative movement.

With regard to claim 24, the springs as claimed are met by the connecting means (4) of Perren.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,123,926) in view of Steffee (US 5,443,514) or Pisharodi (US 5,653,762). Pisharodi meets the claim language as explained supra but fails to disclose a step of rotating the implant after insertion but does teach rolling the implant into a rectangular shape. However, Steffee (see the abstract and the figures) or Pisharodi ('762) (see the abstract and figures) teaches that it was known to reorient similar implants after insertion so that the vertebra engaging elements are oriented in the proper manner. Therefore, it is the Examiner's position that it would have been obvious to insert and reorient the implant of Pisharodi ('926) for the same reasons that Pisharodi

('726) or Steffee does the same, that is, to enable the use of a smaller incision that produces less trauma to the patient.

Regarding claim 30, compression of the implant is inherent to Pisharodi's ('926) device because have to be assembled into the form of Figure 2 before the bands (14) are placed thereover as in Figure 4. Alternatively, the compression of the insert would have been considered clearly obvious to an ordinary artisan.

Regarding claim 33, the flanges on the spikes (8) limit the movement thereof away from the implant; see Figure 2.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi ('926), Steffee, and Pisharodi ('514) as applied to claims 2 and 28-34 above, and further in view of Muhanna (US 6,936,070). Pisharodi ('926) fails to teach the step of filling the space around an implant with a hydrogel as claimed. However, Muhanna teaches that is was known to fill a space around a similar implant with collagen gel, which is a type of hydrogel; see column 7, lines 3-19. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to fill any space around either of the Pisharodi implant with collagen gel for the same reasons that Muhanna does the same or to aid in the cushioning effect desired.

With regard to claim 21, collagen gel is considered to be a protein polymer or a collagen matrix to the extent that this language can be given patentable weight.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi ('926), Steffee, Pisharodi ('514) and Muhanna (US 6,936,070) as applied to claims 20 and 21 above, and further in view of Haldimann (US 6,428,576).

Pisharodi ('926) fails to disclose the use of an adhesive in the implantation method to contact the remaining disk or to seal an opening as claimed. However, Haldimann teaches that it was known to use medical grade adhesives to contact the disk and to seal openings; see Figure 1 and column 4, lines 27-48. Therefore, it is the Examiner's position that it would have been obvious to use the medical grade adhesive of Haldimann to contact the disk and to seal any openings in order to prevent migration of the implant or further herniation of the disk or for the same reasons that Haldimann utilizes the same.

#### ***Response to Arguments***

Applicant's arguments filed August 19, 2008 have been fully considered but they are not persuasive.

The Applicant argues that there is a difference in the Perren device from that of the present invention because the present invention functions differently. Upon further consideration, the Examiner concluded that the claims are still read on by Perren. For this reason, the rejection has been maintained. The mere functional difference does not distinguish a claimed device from the prior art when that functional difference does not clearly suggest a different structure. When the prior art is capable of performing the same function, the claim language is fully met even if the claimed function is not specifically taught by the prior art.

#### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be

applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/  
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